

CASE DEFINITION FOR ADVERSE DRUG REACTIONS – SERIOUS AND LIFE-THREATENING

Serious and life-threatening adverse drug reactions (ADRs)* in an infant or child 18 years or less, associated with the use of prescription, non-prescription, biological (immunoglobulins) products, complementary medicines (including herbals), and radio-pharmaceutical products.

Report even if you are not certain if the product caused the adverse reaction or you do not have all the reporting details.

Exclusions: Do not report reactions due to medical devices, blood products (platelets, red cells, single donor plasma), vaccines, poisonings or self-administered overdoses.

* **Noxious and unintended severe** response to a drug which occurs at any dose and results in emergency observation, hospitalization, persistent or significant disability, or death.